

Application No. 09/872,493
Amendment dated February 28, 2005
Supplemental Reply to Final Office Action of September 10, 2004

Atty Dkt No. ~~1300~~-2329
Bayer No. ~~MST~~-2329

REMARKS

As a preliminary matter, the undersigned attorney would like to thank Examiner Goldberg for the courtesies extended during the Examiner Interview held on February 8, 2005. During the interview, the newly found publication date of the Antao et al. reference was the primary topic of discussion. This Supplemental Amendment is submitted primarily to provide evidence that the present invention antedates the publication date of the Antao et al. reference.

THE PUBLICATION DATE OF THE ANTAO ET AL. REFERENCE

The Antao et al. reference submitted in the Information Disclosure Statement filed on January 15, 2002, had a handwritten publication date of June 1999, with no day provided. The Antao et al. reference was originally cited in the International Search Report in the counterpart PCT application and was submitted to the Office in the IDS filed on January 12, 2002 (reference "AN").

As a result of discussions with Examiner Goldberg on January 28, 2005, and January 31, 2005, the undersigned attorney started to investigate the exact publication date of the Antao et al. reference. As part of the investigation, the undersigned attorney contacted the publisher of the book that the Antao et al. reference was published in. The Antao et al. reference, titled *In Situ Hybridization Using the bDNA Technology*, was published in the book *TECHNIQUES IN QUANTIFICATION AND LOCALIZATION OF GENE EXPRESSION*; the editor of the book is Bruce K. Patterson, M.D. and the book was published by Birkhauser Boston on January 21, 2000. At Appendix A, there is attached an e-mail from Mr. James Clemons, a Customer Service Representative for the Springer Publishing Group, which includes the Birkhauser Boston Publishing House, to the undersigned attorney that shows that the date of publication of the book that included the Antao et al. article was actually January 21, 2000, not June 1999.

Attached at Appendix B is a print-out of a website pages that show that Birkhauser Boston is part of the Springer Publishing Group. Within Appendix B, there is a print-out of a Google Search for "Birkhauser Boston" and selected website pages from the Google Search (the selected pages are highlighted in yellow on the Google Search webpage print-out). The website found at the URL www.phc.vcu.edu/meresearch/Birkhauser.html has the phone number for Birkhauser Boston listed as 1-617-876-2333 and 1-800-SPRINGER. When the 617 number is called, the answering service identifies the number as belonging to the Cambridge office of Springer and Birkhauser and the when the 800 number is called, the answering service identifies the number as belonging to Springer. Similarly, the website found at the URL www.birkhauser.com on the Google Search redirects the visitor to the URL www.springeronline.com/sgw/cda/frontpage/0,11855,4-40290-0-0,00.html?referer=www.birkhauser.com.

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The home page for www.springeronline.com has a link for Birkhauser that also brings the visitor to the URL www.springeronline.com/sgw/cda/frontpage/0,11855,4-40290-0-0-00.html?referer=www.birkhauser.com. The webpages attached at Appendix B demonstrate that the Birkhauser Boston publishing house is part of the Springer Publishing Group.

As a result of the January 21, 2000, publication date of the Antao et al. reference, with this Supplemental Amendment, applicants are submitting Declarations under 37 C.F.R. § 1.131 by all of the inventors that show that the present invention predates the publication date of Antao et al. The Declaration of Daryn Kenny includes six pages from the laboratory notebooks kept by Bayer Corporation that document the experiments that led to the present invention. The laboratory pages have been redacted so as not to disclose the date of execution and witnessing of the pages; however, the Declarants, who have viewed the unredacted pages are providing their declarations that the pages were executed and witnessed prior to January 21, 2000.

Because the instant application was filed less than one year prior to the January 21, 2000, publication date of Antao et al., the Antao et al. reference is a reference under 35 U.S.C. § 102(a) that may be antedated by proof of prior invention. The Declarations under 37 C.F.R. § 1.131 will serve to remove Antao et al. as prior art against the claimed invention by showing that the present invention predates the January 21, 2000, publication date of Antao et al.

With the removal of Antao et al. as prior art, the Examiner's rejection of claims Claims 1, 3-4, 6-23 as obvious over Antao et al. in view of Xu et al. requires reconsideration; accordingly, a new analysis is set forth in this Supplemental Amendment. The remaining traversals in the Amendment filed on December 10, 2004, are not affected by the removal of Antao et al. and thus, require no further consideration over the arguments set forth in the prior Amendment.

THE CLAIM AMENDMENTS

Claim 1 has been amended to remove the term "human sequences of interest." Claim 27 has been amended to emphasize that the method is used to detect the position of a nucleic acid analyte within a "cell." Support for the change to claim 27 is found in the specification at *inter alia*, page 16, line 11-25. No new matter has been added to the application with the changes to the claims set forth herein.

THE REJECTION OVER ANTAO ET AL. IN VIEW OF XU ET AL.

Claims 1, 3-4, 6-23, and 27-33 stand rejected under 35 U.S.C. § 103(a) as obvious over Antao et al. in view of Xu et al. This rejection is respectfully traversed.

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As recited in independent claim 1, the present invention relates to a method for *in situ* detection of a nucleic acid analyte within a sample of biological material using bDNA hybridization... wherein the nucleic acid analyte is selected from the group consisting of DNA, human sequences of interest, endogenous genes, and segments thereof.

As recited in independent claim 27, the present invention relates to a method for *identifying the position of a nucleic acid analyte within a sample of biological material* using bDNA hybridization.

As recited in independent claim 28, the present invention relates to a method for *detecting a nucleic acid analyte within a sample of biological material* comprising performing bDNA hybridization to detect the nucleic acid analyte *in situ*, wherein the *method has a sensitivity sufficient to detect from about 1 to about 10 copies of the nucleic acid analyte in the biological material*.

With the elimination of Antao et al., applicants submit that Xu et al. does not render the claimed invention obvious.

Xu et al. teaches *in situ* hybridization of mRNA with hapten-labeled probes, such as digoxigenin-UTP, fluorescein-UTP, or biotin-UTP. The Examiner originally cited Xu et al. for the hybridization conditions set forth therein.

Xu et al. does not teach or suggest any of the following: the use of bDNA for signal amplification of the mRNA, the use of *in situ* hybridization for the detection of DNA, the use of the procedures described therein to identify the position of the mRNA within a cell, or the use of the procedures described therein to detect about 1 to about 10 copies of the mRNA within a cell; accordingly, it follows that Xu et al. does not teach or suggest the claimed invention.

Because the invention as recited in independent claim 1 et seq., independent claim 27, and independent claim 28 et seq. is not rendered obvious by Xu et al., applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION:

With this supplemental amendment, applicants are providing evidence to establish that the Antao et al. reference has a publication date of January 21, 2000, and the present invention predates the Antao et al. reference. The arguments, amendments, and evidence presented in this Amendment and the prior Amendment filed on December 21, 2004, establish that the claimed invention is not rendered obvious by the cited references. Because the application will be in condition for allowance upon entry of this amendment, applicants respectfully request reversal of all claim rejections and passage of this application to issue.

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Should the Examiner have any questions concerning this response, she is welcome to contact the undersigned attorney at 650-330-4913 or at canaan@reedpatent.com.

Respectfully submitted,

By: Karen Canaan
Karen Canaan
Registration No. 42,382

REED IP LAW GROUP
800 Menlo Avenue, Suite 210
Menlo Park, California 94025
(650) 330-0900 Telephone
(650) 330-0980 Facsimile